PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing (*day/month/year*)	22 MAR 2005
Applicant's or agent's file reference 2815-66242-02	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date (*day/month/year*)	Priority date (*day/month/year*)
PCT/US04/25062	02 August 2004 (02.08.2004)	04 August 2003 (04.08.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): G01N 27/00, 33/53 and US Cl.: 422/82.01; 435/7.1

Applicant

MAKI ET AL.

1. This opinion contains indications relating to the following items:

- [X] Box No. I — Basis of the opinion
- [ ] Box No. II — Priority
- [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV — Lack of unity of invention
- [X] Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI — Certain documents cited
- [ ] Box No. VII — Certain defects in the international application
- [ ] Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(*b*) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-8300	Authorized officer Melanie Yu Telephone No. (571) 272-2933

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/25062

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ in written format

      ☐ in computer readable form

   c. time of filing/furnishing

      ☐ contained in international application as filed.

      ☐ filed together with the international application in computer readable form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/25062

Box No. V Reasoned statement under Rule 43 *bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 9,11,17-20,23,26-28,30,33-35,43-54,61	YES
	Claims 1-8,10,12-16,21-22,24-25,29,31-32,36-42,55-60	NO
Inventive step (IS)	Claims NONE	YES
	Claims 1-61	NO
Industrial applicability (IA)	Claims 1-61	YES
	Claims NONE	NO

2. Citations and explanations:

Claims 1-8, 10, 12-16, 21-22, 24-25, 29, 31-32, 36-42 and 55-60 lack novelty under PCT Article 33(2) as being anticipated by Sullivan et al. (US 2003/0153024). Sullivan et al. teach a device for detecting biomolecules comprising a detection surface ([0022]); a molecular layer immobilized on the detection surface ([0034]); and a signal molecule in a containment area produced from a signal probe ([0038]). Sullivan et al. also teach a biomolecule and a signal template comprising a DNA template ([0035]) and the signal molecule is produced through *in vitro* transcription of the DNA template ([0004]). Sullivan et al. also teach a detection surface being a conductor (electrodes, [0044]) or semiconductor ([0035]). Sullivan et al. teach different affinity binding molecules such as an RNA aptamer ([0005]), protein ([0009]), or an antibody ([0039]) and different spacer molecules ([0006]). Sullivan et al. also teach the DNA molecule template directly or indirectly linked to a biomolecule ([0035]) and a recognition component comprising an enzyme ([0049]), nucleic acid ([0034]), or a protein ([0035]). Sullivan et al. teach a reference voltage provided to a circuit ([0044]), and the containment area being a reaction vessel ([0003]). Sullivan et al. teach a method comprising: immobilizing a target in a reaction vessel ([0010]); contacting the target with a signal probe ([0008]); producing a signal molecule using a signal template ([0022]); and detecting the signal molecule at the detection surface ([0022]).

Claims 9, 11, 17-20, 23, 26-28, 30, 33-35 and 43-46 lack an inventive step under PCT Article 33(3) as being obvious over Sullivan et al. (US 2003/0153024). Sullivan et al. teach a device for detecting biomolecules, but fail to teach specific conductor and semiconductor materials, affinity binding molecules, spacer molecules, and recognition components. However, it would have been obvious to use known materials, molecules, and components such as peptides or organic polymers, which are functional equivalents to the materials, molecules, and components taught by Sullivan et al.